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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,733	10/29/2003	Martin J. MacPhee	CI-0019C5	2650

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EXAMINER	
MCKANE, ELIZABETH L	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,733	MACPHEE ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *102903*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification fails to support the limitation of claims 1-3, "wherein said effective rate is not constant for the duration of the sterilization procedure" or the limitation of claim 22, which further limits the rate of claim 22, such that the irradiation rate changes from 3.0 kGy/hr to 2.0 kGy/hr. The specification fails to support these limitations. Specifically, in lines 10-12 on page 14 of the specification, teaches "[p]referably, the rate of irradiation is constant for the duration of the sterilization procedure." While one may assert that a non-constant rate is merely a non-preferable embodiment of the instant invention, there is no teaching elsewhere in the specification of how or why one would choose a non-constant rate, or when choosing a non-constant rate, which rates to choose. Moreover, each and every example in the specification also teaches using only a constant rate of irradiation. Therefore, the specification fails to describe an effective rate that is not constant for the duration of the sterilization procedure.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-3 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are rejected for the same reasons set forth in the paragraphs above with respect to the objection to the specification.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 2, 6-11, 18-22, 24, 33, and 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, and 13 of U.S. Patent No. 6,682,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the instant claims is encompassed in its entirety by the subject matter of the patent.

6. Claims 1-25 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/694,398.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The copending application claims are drawn to sterilization of a preparation containing albumin while the instant claims are drawn to sterilization of a blood component. Since albumin is a blood component, the instant claims are encompassed by the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-25 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/694,734.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The copending application claims are drawn to sterilization of a preparation containing albumin while the instant claims are drawn to sterilization of a blood component. Since albumin is a blood component, the instant claims are encompassed by the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-25 and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 114-139 of copending Application No. 10/457,451.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The copending application claims are drawn to sterilization fetal bovine serum while the instant claims are drawn to sterilization of a blood component. Since fetal bovine serum is a blood component, the instant claims are encompassed by the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

10. Claims 1-36 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-36 of copending Application No. 10/694,391. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1, 4, 6, 7, 9-17, and 23-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al in view of Block ("Disinfection, Sterilization, and Preservation" 4th ed.) and Sakai et al("Microbiological Studies on Drugs and Their Raw Materials. IV. Sterilization of Microbial Contaminants in Enzyme Powder by Gamma Irradiation").

Platz et al teaches a method for sterilizing blood products (col.1, lines 17-27) wherein the product may be lyophilized to less than 3% moisture (natural water and fluids removed) or frozen before irradiation. See col.3, lines 38-47. Blood products that may be treated include red

blood cells, serum, plasma, protein fractions, immune globulins, Factor VIII, and Factor IX. See Abstract; col.17, line 66 to col.18, line 36. The product may be irradiated at ambient temperature or in the deep frozen state. In addition, a chemical sensitizer may be added to the blood product before irradiation. See col.4, lines 17-26. The radiation used may be ionizing radiation, such as gamma radiation. See col.17, lines 57-60. Platz et al specifically names fetal bovine serum as a blood product that may be sterilized by the method (col.1, lines 24-25). Platz et al further discloses that the lyophilized product be kept under nitrogen or other inert gas (col.20, lines 54-60). It would have been obvious to keep the product under these conditions while irradiating as well, in order to avoid formation of hydroxyl radicals by the gamma radiation (col.3, lines 6-8). Moreover, it is deemed obvious to use argon as the inert gas since argon is a well-known inert gas. Platz et al is silent with respect to a dose rate at which to sterilize the blood products.

Sakai et al teaches a method for sterilizing lyophilized enzyme powder by gamma irradiation at a dose rate of 3.45×10^4 rad/hr (0.345 kGy/hr). See page 1131, "γ-Irradiation and Dose Assay". As Sakai et al teaches a gamma irradiation dose rate for the sterilization of a lyophilized sensitive biological material, it is deemed obvious to one of ordinary skill in the art to employ the dose rate disclosed by Sakai et al in the method of Platz et al, as this dose rate has been determined to be effective in removing microbial contamination while preserving the activity of the sensitive biological material.

As to the dose rate being not constant for the duration of the sterilization procedure, Block evidences that the most common source of gamma radiation for microbial inactivation is ^{60}Co. See page 567, first full paragraph. As ^{60}Co is a decaying source of radiation, the rate of radiation is constantly decreasing and thus is not constant. It would have been obvious for one of

ordinary skill in the art to use a ^{60}Co source as the source of γ-radiation, as Block evidences that it is the most common source used.

15. Claims 1, 4, 6, 8, 10-17, 23-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al in view of Block ("Disinfection, Sterilization, and Preservation" 4th ed.) and Chanderkar et al ("The Involvement of Aromatic Amino Acids in Biological Activity of Bovine Fibrinogen as Assessed by Gamma-Irradiation").

Platz et al teaches a method for sterilizing blood products (col.1, lines 17-27) wherein the product may be lyophilized to less than 3% moisture (natural water and fluids removed) or frozen before irradiation. See col.3, lines 38-47. Blood products that may be treated include red blood cells, serum, plasma, protein fractions, immune globulins, Factor VIII, and Factor IX. See Abstract; col.17, line 66 to col.18, line 36. The product may be irradiated at ambient temperature or in the deep frozen state. In addition, a chemical sensitizer may be added to the blood product before irradiation. See col.4, lines 17-26. The radiation used may be ionizing radiation, such as gamma radiation. See col.17, lines 57-60. Platz et al specifically names fetal bovine serum as a blood product that may be sterilized by the method (col.1, lines 24-25). Platz et al further discloses that the lyophilized product be kept under nitrogen or other inert gas (col.20, lines 54-60). It would have been obvious to keep the product under these conditions while irradiating as well, in order to avoid formation of hydroxyl radicals by the gamma radiation (col.3, lines 6-8). Moreover, it is deemed obvious to use argon as the inert gas since argon is a well-known inert gas. Platz et al is silent with respect to a dose rate at which to sterilize the blood products.

Chanderkar et al teaches gamma ray sterilization of fibrinogen using a dose rate of 12,500 R/min (7.5 kGy/hr). As Chanderkar et al teaches a gamma irradiation dose rate for the

sterilization of a lyophilized sensitive biological material, it is deemed obvious to one of ordinary skill in the art to employ the dose rate disclosed by Chanderkar et al in the method of Platz et al, as this dose rate has been determined to be effective in removing microbial contamination while preserving the activity of the sensitive biological material.

As to the dose rate being not constant for the duration of the sterilization procedure, Block evidences that the most common source of gamma radiation for microbial inactivation is ^{60}Co. See page 567, first full paragraph. As ^{60}Co is a decaying source of radiation, the rate of radiation is constantly decreasing and thus is not constant. It would have been obvious for one of ordinary skill in the art to use a ^{60}Co source as the source of γ-radiation, as Block evidences that it is the most common source used.

16. Claims 1, 4, 6, 7, 9-17, and 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al in view of Block ("Disinfection, Sterilization, and Preservation" 4th ed.) and Patel et al ("Effect of Gamma Radiation and Ethylene Oxide on Papain").

Platz et al teaches a method for sterilizing blood products (col.1, lines 17-27) wherein the product may be lyophilized to less than 3% moisture (natural water and fluids removed) or frozen before irradiation. See col.3, lines 38-47. Blood products that may be treated include red blood cells, serum, plasma, protein fractions, immune globulins, Factor VIII, and Factor IX. See Abstract; col.17, line 66 to col.18, line 36. The product may be irradiated at ambient temperature or in the deep frozen state. In addition, a chemical sensitizer may be added to the blood product before irradiation. See col.4, lines 17-26. The radiation used may be ionizing radiation, such as gamma radiation. See col.17, lines 57-60. Platz et al specifically names fetal bovine serum as a blood product that may be sterilized by the method (col.1, lines 24-25). Platz et al further

discloses that the lyophilized product be kept under nitrogen or other inert gas (col.20, lines 54-60). It would have been obvious to keep the product under these conditions while irradiating as well, in order to avoid formation of hydroxyl radicals by the gamma radiation (col.3, lines 6-8). Moreover, it is deemed obvious to use argon as the inert gas since argon is a well-known inert gas. Platz et al is silent with respect to a dose rate at which to sterilize the blood products.

Patel et al discloses a method for the sterilization of papain wherein the enzyme is irradiated with gamma radiation at a dose rate of 0.29 Mrad/hr (2.9 kGy/hr, "about 3.0 kGy/hr" or "about 2.0 kGy/hr"). See page 81, last paragraph. As Patel et al teaches a gamma irradiation dose rate for the sterilization of a sensitive biological material, it is deemed obvious to one of ordinary skill in the art to employ the dose rate disclosed by Patel et al in the method of Platz et al, as this dose rate has been determined to be effective in removing microbial contamination while preserving the activity of the sensitive biological material.

As to the dose rate being not constant for the duration of the sterilization procedure, Block evidences that the most common source of gamma radiation for microbial inactivation is ^{60}Co. See page 567, first full paragraph. As ^{60}Co is a decaying source of radiation, the rate of radiation is constantly decreasing and thus is not constant. It would have been obvious for one of ordinary skill in the art to use a ^{60}Co source as the source of γ-radiation, as Block evidences that it is the most common source used.

17. Claims 2-7, 9-20, and 23-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al in view of Horowitz et al (U.S. Patent No. 5,712,086), Block, and Sakai et al.

Platz et al teaches a method for sterilizing blood products (col.1, lines 17-27) wherein the

product may be lyophilized to less than 3% moisture (natural water and fluids removed) or frozen before irradiation. See col.3, lines 38-47. Blood products that may be treated include red blood cells, serum, plasma, protein fractions, immune globulins, Factor VIII, and Factor IX. See Abstract; col.17, line 66 to col.18, line 36. The product may be irradiated at ambient temperature or in the deep frozen state. In addition, a chemical sensitizer may be added to the blood product before irradiation. See col.4, lines 17-26. The radiation used may be ionizing radiation, such as gamma radiation. See col.17, lines 57-60. Platz et al specifically names fetal bovine serum as a blood product that may be sterilized by the method (col.1, lines 24-25). Platz et al further discloses that the lyophilized product be kept under nitrogen or other inert gas (col.20, lines 54-60). It would have been obvious to keep the product under these conditions while irradiating as well, in order to avoid formation of hydroxyl radicals by the gamma radiation (col.3, lines 6-8). Moreover, it is deemed obvious to use argon as the inert gas since argon is a well-known inert gas. Platz et al is silent with respect to a dose rate at which to sterilize the blood products, using a stabilizer, and removing an organic solvent from the tissue prior to irradiation.

Horowitz et al discloses a method of using ionizing radiation (such as gamma) in combination with a stabilizer (quencher) for the sterilization of sensitive biological material. See Abstract; col.6, lines 55-62. The quencher may be mannitol, glutathione, flavonoids, etc. See col.7, lines 3-8. Horowitz et al further teaches that the stabilizers react with both free radicals and reactive forms of oxygen (col.6, line 66 to col.7, line 2), thereby protecting the biological material. For this reason, one of ordinary skill in the art would have found it obvious to use a stabilizer in the method of Platz et al. Horowitz et al further teaches that blood products are first subjected to organic solvent fractionation in order to separate them (col.6, lines 17-21). As these

same blood products are treated by the sterilization method of Platz et al, it would have been obvious that, in order to obtain them, it would have been necessary to subject them to organic solvent fractionation.

Sakai et al teaches a method for sterilizing lyophilized enzyme powder by gamma irradiation at a dose rate of 3.45×10^4 rad/hr (0.345 kGy/hr). See page 1131, "γ-Irradiation and Dose Assay". As Sakai et al teaches a gamma irradiation dose rate for the sterilization of a lyophilized sensitive biological material, it is deemed obvious to one of ordinary skill in the art to employ the dose rate disclosed by Sakai et al in the method of Platz et al, as this dose rate has been determined to be effective in removing microbial contamination while preserving the activity of the sensitive biological material.

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18. Claims 2-6, 8, 10-20, and 23-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al in view of Horowitz et al (U.S. Patent No. 5,712,086), Block, and Chanderkar et al.

Platz et al teaches a method for sterilizing blood products (col.1, lines 17-27) wherein the product may be lyophilized to less than 3% moisture (natural water and fluids removed) or frozen before irradiation. See col.3, lines 38-47. Blood products that may be treated include red

blood cells, serum, plasma, protein fractions, immune globulins, Factor VIII, and Factor IX. See Abstract; col.17, line 66 to col.18, line 36. The product may be irradiated at ambient temperature or in the deep frozen state. In addition, a chemical sensitizer may be added to the blood product before irradiation. See col.4, lines 17-26. The radiation used may be ionizing radiation, such as gamma radiation. See col.17, lines 57-60. Platz et al specifically names fetal bovine serum as a blood product that may be sterilized by the method (col.1, lines 24-25). Platz et al further discloses that the lyophilized product be kept under nitrogen or other inert gas (col.20, lines 54-60). It would have been obvious to keep the product under these conditions while irradiating as well, in order to avoid formation of hydroxyl radicals by the gamma radiation (col.3, lines 6-8). Moreover, it is deemed obvious to use argon as the inert gas since argon is a well-known inert gas. Platz et al is silent with respect to a dose rate at which to sterilize the blood products, using a stabilizer, and removing an organic solvent from the tissue prior to irradiation.

Horowitz et al discloses a method of using ionizing radiation (such as gamma) in combination with a stabilizer (quencher) for the sterilization of sensitive biological material. See Abstract; col.6, lines 55-62. The quencher may be mannitol, glutathione, flavonoids, etc. See col.7, lines 3-8. Horowitz et al further teaches that the stabilizers react with both free radicals and reactive forms of oxygen (col.6, line 66 to col.7, line 2), thereby protecting the biological material. For this reason, one of ordinary skill in the art would have found it obvious to use a stabilizer in the method of Platz et al. Horowitz et al further teaches that blood products are first subjected to organic solvent fractionation in order to separate them (col.6, lines 17-21). As these same blood products are treated by the sterilization method of Platz et al, it would have been

obvious that, in order to obtain them, it would have been necessary to subject them to organic solvent fractionation.

Chanderkar et al teaches gamma ray sterilization of fibrinogen using a dose rate of 12,500 R/min (7.5 kGy/hr). As Chanderkar et al teaches a gamma irradiation dose rate for the sterilization of a lyophilized sensitive biological material, it is deemed obvious to one of ordinary skill in the art to employ the dose rate disclosed by Chanderkar et al in the method of Platz et al, as this dose rate has been determined to be effective in removing microbial contamination while preserving the activity of the sensitive biological material.

As to the dose rate being not constant for the duration of the sterilization procedure, Block evidences that the most common source of gamma radiation for microbial inactivation is ^{60}Co. See page 567, first full paragraph. As ^{60}Co is a decaying source of radiation, the rate of radiation is constantly decreasing and thus is not constant. It would have been obvious for one of ordinary skill in the art to use a ^{60}Co source as the source of γ-radiation, as Block evidences that it is the most common source used.

19. Claims 2-7 and 9-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al in view of Horowitz et al (U.S. Patent No. 5,712,086), Block, and Patel et al.

Platz et al teaches a method for sterilizing blood products (col.1, lines 17-27) wherein the product may be lyophilized to less than 3% moisture (natural water and fluids removed) or frozen before irradiation. See col.3, lines 38-47. Blood products that may be treated include red blood cells, serum, plasma, protein fractions, immune globulins, Factor VIII, and Factor IX. See Abstract; col.17, line 66 to col.18, line 36. The product may be irradiated at ambient temperature or in the deep frozen state. In addition, a chemical sensitizer may be added to the blood product

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Horowitz et al discloses a method of using ionizing radiation (such as gamma) in combination with a stabilizer (quencher) for the sterilization of sensitive biological material. See Abstract; col.6, lines 55-62. The quencher may be mannitol, glutathione, flavonoids, etc. See col.7, lines 3-8. Horowitz et al further teaches that the stabilizers react with both free radicals and reactive forms of oxygen (col.6, line 66 to col.7, line 2), thereby protecting the biological material. For this reason, one of ordinary skill in the art would have found it obvious to use a stabilizer in the method of Platz et al. Horowitz et al further teaches that blood products are first subjected to organic solvent fractionation in order to separate them (col.6, lines 17-21). As these same blood products are treated by the sterilization method of Platz et al, it would have been obvious that, in order to obtain them, it would have been necessary to subject them to organic solvent fractionation.

Patel et al discloses a method for the sterilization of papain wherein the enzyme is irradiated with gamma radiation at a dose rate of 0.29 Mrad/hr (2.9 kGy/hr, "about 3.0 kGy/hr"

or "about 2.0 kGy/hr"). See page 81, last paragraph. As Patel et al teaches a gamma irradiation dose rate for the sterilization of a sensitive biological material, it is deemed obvious to one of ordinary skill in the art to employ the dose rate disclosed by Patel et al in the method of Platz et al, as this dose rate has been determined to be effective in removing microbial contamination while preserving the activity of the sensitive biological material.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (6:30 am-4:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leigh McKane

Leigh McKane
Primary Examiner
Art Unit 1744

elm
20 March 2005